

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: David A. Edwards and Jeffrey S. Hrkach
Application No.: 09/822,716 Group: 1615
Filed: March 30, 2001 Examiner: Pulliam, A.
Confirmation No.: 7248

Title: PARTICLES FOR INHALATION HAVING SUSTAINED RELEASE PROPERTIES



CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202	
on <u>4/9/03</u> Date	<u>Rachel Cohen</u> Signature
<u>RACHEL COHEN</u> Typed or printed name of person signing certificate	

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SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
P.O. Box 2327
Arlington, VA 22202

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☐ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☒ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☒ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

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Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
 - ☒ Copies of the cited references are enclosed.
 - ☐ Copies of cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
 - ☐ The listed references was cited in the enclosed International Search Report in a counterpart foreign application.
 - ☐ The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☐ the enclosed English language abstract.

[X] Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. 09/383,054, by David A. Edwards and Jeffrey S. Hrkach,
filed August 25, 1999, Docket No.: 2685.1003-001

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

[X] A copy of each above-cited application, including the current claims, is enclosed.

[] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

[X] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

[] Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.

[X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By 

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Concord, MA 01742-9133

Dated: 4/9/03

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 2685.1003-008		APPLICATION NO. 09/822,716	
SECOND SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION April 2, 2003 (Use several sheets if necessary)		APPLICANT David A. Edwards, et al.			
		FILING DATE March 30, 2001		CONFIRMATION NO. 7248	
U.S. PATENT DOCUMENTS					
EXAM- INER INI- TIAL		DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME	
	BA	2,470,296	05/17/49	Fields	
	BB	2,533,065	12/05/50	Taplin et al.	
	BC	2,992,645	07/18/61	Fowler	
	BD	3,781,230	12/25/73	Vassiliades et al.	
	BE	3,957,965	05/18/76	Harley et al.	
	BF	4,009,280	02/22/77	Macarthur et al.	
	BG	4,089,800	05/16/78	Temple	
	BH	4,161,516	07/17/79	Bell	
	BI	4,173,488	11/06/79	Vassiliades et al.	
	BJ	4,272,398	06/09/81	Jaffe	
	BK	4,352,883	10/05/82	Lim	
	BA2	4,391,909	07/05/83	Lim	
	BB2	4,466,442	08/21/84	Hilmann et al.	
	BC2	4,480,041	10/30/84	Myles et al.	
	BD2	4,524,769	06/25/85	Wetterlin	
	BE2	4,572,203	02/25/86	Feinstein	
	BF2	4,590,206	05/20/86	Forrester et al.	
	BG2	4,615,697	10/07/86	Robinson	
	BH2	4,679,555	07/14/87	Sackner	
	BI2	4,741,872	05/03/88	De Luca et al.	
	BJ2	4,743,545	05/10/88	Torobin	
	BK2	4,774,958	10/04/88	Feinstein	
	BA3	4,789,550	12/06/88	Hommel et al.	
	BB3	4,818,542	04/04/89	De Luca et al.	
	BC3	4,847,091	07/11/89	Illum	
	BD3	4,855,144	08/08/89	Leong et al.	
	BE3	4,857,311	08/15/89	Domb et al.	
EXAMINER			DATE CONSIDERED		

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U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
	BF3	4,861,627	08/29/89	Mathiowitz et al.
	BG3	4,865,789	09/12/89	Castro et al.
	BH3	This reference number intentionally left blank		
	BI3	4,904,479	02/27/90	Illum
	BJ3	4,917,119	04/17/90	Potter et al.
	BK3	4,963,297	10/16/90	Madden
	BA4	4,976,968	12/11/90	Steiner
	BB4	4,994,281	02/19/91	Muranishi et al.
	BC4	This reference number intentionally left blank		
	BD4	5,033,463	07/23/91	Cocozza
	BE4	5,064,650	11/12/91	Lew
	BF4	5,069,936	12/03/91	Yen
	BG4	5,075,109	12/24/91	Tice et al.
	BH4	5,100,669	03/31/92	Hyon et al.
	BI4	5,123,414	06/23/92	Unger
	BJ4	5,145,684	09/08/92	Liversidge et al.
	BK4	5,160,745	11/03/92	De Luca et al.
	BA5	5,169,871	12/08/92	Hughes et al.
	BB5	5,174,988	12/29/92	Mautone et al.
	BC5	5,195,520	03/23/93	Schlieff et al.
	BD5	5,204,108	04/20/93	Illum
	BE5	5,204,113	04/20/93	Hartley et al.
	BF5	5,260,306	11/09/93	Boardman et al.
	BG5	5,271,961	12/21/93	Mathiowitz et al.
	BH5	5,306,483	04/26/94	Mautone
	BI5	5,327,883	07/12/94	Williams et al.
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EXAM- INER INI- TIAL		DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
	BJ5	5,334,381	08/02/94	Unger
	BK5	5,340,587	08/23/94	Milhalko et al.
	BA6	5,352,435	10/04/94	Unger
	BB6	5,384,133	01/24/95	Boyes et al.
	BC6	5,393,524	02/28/95	Quay
	BD6	5,407,609	04/18/95	Tice et al.
	BE6	5,456,917	10/10/95	Wise et al.
	BF6	5,466,841	11/14/98	Horrobin et al.
	BG6	5,482,946	01/09/96	Clark et al.
	BH6	5,518,709	05/21/96	Sutton et al.
	BI6	5,518,998	05/21/96	Bäckström et al.
	BJ6	5,551,489	09/03/96	Trofast et al.
	BK6	5,580,575	12/03/96	Unger et al.
	BA7	5,607,695	03/04/97	Ek et al.
	BB7	5,607,915	03/04/97	Patton
	BC7	5,612,053	03/18/97	Baichwal et al.
	BD7	5,614,216	03/25/97	Janoff
	BE7	5,654,007	08/05/97	Johnson
	BF7	5,690,954	11/25/97	Illum
	BG7	5,698,721	12/16/97	Heath
	BH7	5,707,644	01/13/98	Illum
	BI7	5,709,884	01/20/98	Trofast et al.
	BJ7	5,780,014	07/14/98	Eljamal
	BK7	5,795,594	08/18/98	York et al.
	BA8	5,804,212	09/08/98	Illum
	BB8	5,814,607	09/29/98	Patton
EXAMINER			DATE CONSIDERED	

PTO-1449 REPRODUCED SECOND SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION April 2, 2003 (Use several sheets if necessary)		ATTORNEY DOCKET NO. 2685.1003-008	APPLICATION NO. 09/822,716	
		APPLICANT David A. Edwards, et al.		
		FILING DATE March 30, 2001	CONFIRMATION NO. 7248	GROUP 1615
U.S. PATENT DOCUMENTS				
EXAM- INER INI- TIAL		DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
	BC8	5,830,853	11/03/98	Bäckström, et al.
	BD8	5,851,453	12/22/98	Hanna, et al.
	BE8	This reference number intentionally left blank		
	BF8	5,874,063	02/23/99	Briggner et al.
	BG8	This reference number intentionally left blank		
	BH8	5,885,613	03/23/99	Holland et al.
	BI8	5,902,802	05/11/99	Heath
	BJ8	5,922,354	07/13/99	Johnson
	BK8	5,928,469	07/27/99	Franks et al.
	BA9	This reference number intentionally left blank		
	BB9	This reference number intentionally left blank		
	BC9	This reference number intentionally left blank		
	BD9	5,993,783	11/30/99	Eljamal
	BE9	This reference number intentionally left blank		
	BF9	This reference number intentionally left blank		
	BG9	This reference number intentionally left blank		
	BH9	6,019,968	02/01/00	Platz
	BI9	This reference number intentionally left blank		
	BJ9	6,051,256	04/18/00	Platz
	BK9	6,063,138	05/16/00	Hanna et al.
	BA10	This reference number intentionally left blank		
	BB10	6,080,721	06/27/00	Patton
	BC10	This reference number intentionally left blank		
EXAMINER			DATE CONSIDERED	

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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES NO
	BL	WO 80/02365	13/11/80	PCT			
	BM	WO 86/06959	04/12/86	PCT			
	BN	WO 88/04556	30/06/88	PCT			
	BO	WO 88/09163	01/12/88	PCT			
	BP	WO 91/04732	18/04/91	PCT			
	BQ	WO 91/06286	16/05/91	PCT			
	BL2	WO 91/06287	16/05/91	PCT			
	BM2	WO 91/12823	05/09/91	PCT			
	BN2	This reference number intentionally left blank					
	BO2	WO 92/18164	29/10/92	PCT			
	BP2	WO 92/21382	10/12/92	PCT			
	BQ2	WO 93/25221	23/12/93	PCT			
	BL3	WO 94/04133	03/03/94	PCT			
	BM3	WO 94/07514	14/04/94	PCT			
	BN3	WO 94/08627	28/04/94	PCT			
	BO3	WO 94/16739	04/08/94	PCT			
	BP3	WO 95/00127	05/01/95	PCT			
	BQ3	WO 95/07072	16/03/95	PCT			
	BL4	WO 95/24183	14/09/95	PCT			
	BM4	WO 95/31479	23/11/95	PCT (Platz)			
	BN4	WO 95/35097	28/12/95	PCT			
	BO4	WO 96/09814	04/04/96	PCT			
	BP4	This reference number intentionally left blank					
	BQ4	WO 96/23485	08/08/96	PCT			
	BL5	WO 96/32096	17/10/96	PCT (Eljamal)			
	BM5	WO 96/32116	17/10/96	PCT (Eljamal)			
	BN5	WO 96/32149	17/10/96	PCT (Platz)			

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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	BO5	WO 96/40963	19/12/96	PCT			
	BP5	WO 96/41873	27/12/96	PCT			
	BQ5	WO 97/03649	06/02/97	PCT			
	BL6	WO 97/36574	09/10/97	PCT			
	BM6	This reference number intentionally left blank					
	BN6	WO 98/16205	23/04/98	PCT (Foster)			
	BO6	WO 98/29096	09/07/98	PCT (Gordon)			
	BP6	WO 98/29098	09/07/98	PCT (Gordon)			
	BQ6	WO 98/29140	09/07/98	PCT (Gordon)			
	BL7	WO 98/29141	09/07/98	PCT (Gordon)			
	BM7	This reference number intentionally left blank					
	BN7	WO 98/51278	19/11/98	PCT			
	BO7	WO 99/16419	08/04/99	PCT			
	BP7	WO 99/16420	08/04/99	PCT			
	BQ7	WO 99/16421	08/04/99	PCT			
	BL8	WO 99/16422	08/04/99	PCT			
	BM8	WO 99/66903	29/12/99	PCT			
	BN8	This reference number intentionally left blank					
	BO8	WO 00/15262	23/03/00	PCT (Clark)			
	BP8	WO 00/21594	20/04/00	PCT (Clark)			
	BQ8	WO 00/33811	15/06/00	PCT			
	BL9	WO 01/00312 A1	04/01/01	PCT (Bennett)			
	BM9	WO 01/13891 A3	01/03/01	PCT			
	BN9	WO 01/32144 A1	10/05/01	PCT (Lechuga- Ballesteros)			
EXAMINER				DATE CONSIDERED			

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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO	
	BO9	WO 02/09669 A3	07/02/00	PCT (Snyder)				
	BP9	WO 02/11695 A3	14/02/02	PCT (Stevenson)				
	BQ9	WO 02/054868 A2	18/07/02	PCT (Weickert)				
	BL10	WO 02/055101 A2	18/07/02	PCT (Hastedt)				
	BM10	WO 02/087542 A1	07/11/02	PCT (Bot)				
	BN10	EP 0 072 046 A1	16/02/03	EPO				
	BO10	EP 0 213 303 B1	04/09/91	EPO				
	BP10	EP 0 257 915 A1	02/03/88	EPO				
	BQ10	EP 0 257 956 B1	20/05/92	EPO				
	BL11	EP 0 324 938 A1	26/07/89	EPO				
	BM11	EP 0 335 133 A2	04/10/89	EPO				
	BN11	EP 0 458 745 A1	14/05/91	EPO				
	BO11	EP 0 510 731 A1	28/10/92	EPO				
	BP11	EP 0 634 166 A1	18/01/95	EPO				
	BQ11	EP 0 656 206 A1	07/06/95	EPO				
	BL12	1 288 583	17/11/69	GB				
	BM12	1,300,009	05/05/92	Canada				
	BN12	1,302,258	02/06/92	Canada				
	BO12	2,058,428	05/09/00	Canada				
	BP12	2,085,884	30/12/91	Canada				
	BQ12	2,111,002	22/08/00	Canada				
	BL13	2,126,244	26/09/00	Canada				
	BM13	2,166,108	05/01/95	Canada				
	BN13	2,170,394	02/03/95	Canada				
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

BR	This reference number intentionally left blank.
BS	Adjei, A., and Garren, J., "Pulmonary Delivery of Peptide Drugs: Effect of Particle Size on Bioavailability of Leuprolide Acetate in Healthy Male Volunteers," <i>Pharm. Res.</i> , 7(6):565-569 (1990).
BT	Allen, T.M., et al., "Subcutaneous Administration of Liposomes: A Comparison with the Intravenous and Intraperitoneal Routes of Injection," <i>Biochem. et Biophys. Acta.</i> 1150:9-16 (1993).
BU	Altshuler, B., et al., "Aerosol Deposition in the Human Respiratory Tract," <i>Am. Med. Assoc. Arch. of Indust. Health</i> 15:293-303 (1957).
BV	Anderson, P.J., et al., "Effect of Cystic Fibrosis on Inhaled Aerosol Boluses," <i>Am. Rev. Respir. Dis.</i> , 140:1317-1324 (1989).
BW	Anderson, M., et al., "Human Deposition and Clearance of 6- μ m Particles Inhaled with an Extremely Low Flow Rate," <i>Exp. Lung Res.</i> , 21:187-195 (1995).
BX	Barrera, D.A., et al., "Synthesis and RGD Peptide Modification of a New Biodegradable Copolymer: Poly(lactic acid-co-lysine)," <i>J. Am. Chem. Soc.</i> , 115:11010-11011 (1993).
BY	Beck, L.R., et al., "A New Long-Acting Injectable Microcapsule System for the Administration of Progesterone," <i>Fertility and Sterility</i> , 31(5):545-551 (1979).
BZ	Benita, S., et al., "Characterization of Drug-loaded Poly(D,L-lactide) Microspheres," <i>J. of Pharm. Sci</i> 73(12):1721-1724 (1984).
BR2	Blackett, P.M., and G. Buckton, "A Microcalorimetric Investigation of the Interaction of Surfactants with Crystalline and Partially Crystalline Salbutamol Sulphate in a Model Inhalation Aerosol System," <i>Pharmaceutical Research</i> , 12(11):1689-1693 (1995).
BS2	Brain, J.D., "Physiology and Pathophysiology of Pulmonary Macrophages". In <i>The Reticuloendothelial System</i> , Reichard and Filkins, eds. (Plenum Press, New York), pp. 315-327 (1985).
BT2	Brown, A.R., et al., "Propellant-Driven Aerosols of Functional Proteins as Potential Therapeutic Agents in the Respiratory Tract," <i>Immunopharmacology</i> , 28:241-257 (1994).
BU2	Byron, P.R., "Determinants of Drug and Polypeptide Bioavailability from Aerosols Delivered to the Lung," <i>Adv. Drug. Del. Rev.</i> , 5:107-132 (1990).
BV2	Carroll, B.A., et al., "Gelatin Encapsulated Nitrogen Microbubbles as Ultrasonic Contrast Agents," <i>Investigative Radiology</i> , 15:260-266 (1980).
BW2	Carroll, B.A., et al., "Ultrasonic Contrast Enhancement of Tissue by Encapsulated Microbubbles," <i>Radiology</i> , 143:747-750 (1982).
BX2	Ch'ng, H.S., et al., "Bioadhesive Polymers as Platforms for Oral Controlled Drug Delivery II: Synthesis and Evaluation of Some Swelling, Water-Insoluble Bioadhesive Polymers," <i>J. of Pharm Sci.</i> , 74(4):399-405 (1985).

EXAMINER

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PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 2685.1003-008		APPLICATION NO. 09/822,716	
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		FILING DATE March 30, 2001		CONFIRMATION NO. 7248	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
	BY2	Clark, A., and P. Byron, "Dependence of Pulmonary Absorption Kinetics on Aerosol Particle Size," <i>Z. Erkrank. Atm.org.</i> , 166:13-24 (1986).			
	BZ2	Clark, A.R., and M. Egan, "Modeling the Deposition of Inhaled Powdered Drug Aerosols," <i>J. Aerosol Sci.</i> , 25(1):175-186 (1994).			
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	BT7	Kobayashi, S. et al., "Pulmonary Delivery of Salmon Calcitonin Dry Powders Containing Absorption Enhancers in Rats," <i>Pharm. Res.</i> , 13(1):80-83 (1996).			
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